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TITLE: Transformative Learning: Patterns of Psychophysiological Response and Technology-Enabled Learning and Intervention Systems

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<b>14. ABSTRACT</b>  This research project examines arousal patterns associated with physiological craving and stress. It is hypothesized that biometric data (gathered from wearable sensors) can identify and predict the arousal patterns associated with tobacco use behavior, and that patterns of cue reactivity will allow us to differentiate between psychological craving and physiological arousal in smokers. Four groups of participants (non-smokers, former smokers, current smokers, deprived smokers) participated in both naturalistic and experimental sessions, including: a) a 3-day naturalistic baseline; b) a standardized elicited stress activity; and c) a cue exposure presentation consisting of 12 validated video clips to elicit various types of arousal. Participants rated their perceived craving and arousal levels following exposure to a set of film clips. Multivariate analyses and neural networking will be used to determine psychological and physiological differences between groups.					
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# INTRODUCTION

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Modifiable behaviors, such as smoking, alcohol and obesity are responsible for nearly half of the leading causes of American deaths. Among these behaviors, tobacco use remains the single most preventable cause of death in the United States. Successfully changing one's behavior, however, is a challenging task. It is expected that the data collected from this research project will have direct implications for contributing to effective behavior change interventions.

This study builds on the outcomes of a 2005 pilot study entitled "Physiological and Momentary Assessment for Identifying Tobacco Use Patterns" which sought to detect and predict the physiological antecedents of tobacco use (Jordan, Jerome, & Faraj, 2006). The findings from this study were consistent with previous research that established strong physiologic connections between emotional expression and physiological arousal (e.g., skin conductance, temperature, respiration, blood flow) (Nasoz et al., 2004; Picard, 2001).

Specifically, this project aims to further explore physiological arousal and behavior by comparing interpretations of arousal and craving in smokers and non-smokers. It is hypothesized that biometric data collected from physiological sensors will be able to identify and predict arousal patterns associated with tobacco use behavior.

This annual report describes the research tasks and results from Year 1 activities (August 6, 2007 to August 5, 2008) for the project entitled "Transformative Learning: Patterns of Psychophysiological Response in Technology Enabled Learning and Intervention Systems."

The early stages of the project (August, 2007 to March, 2008) consisted primarily of preparatory work for the data collection phase. This included applying for and receiving protocol approval from both the local IRB and USAMRMC, hiring a Project Manager, and organizing all of the necessary documents (i.e. recruitment materials and standardized scripts) that were required to efficiently run the orientation and laboratory sessions with participants. In order to elicit arousal and craving in a controlled laboratory setting, the research team spent time developing mediated stress activities, comprising of a public speaking exercise and a film clip presentation.

After finding an appropriate rental space for the laboratory room, equipment and supplies were purchased, and training of the newly acquired technologies (i.e., physiological sensors and software programs) took place to ensure competency in implementing the study.

Recruitment of participants began immediately following second tiered human subjects' approval on March 25, 2008. The remainder of Year 1 (April, 2008 to August, 2008) consisted of actively recruiting participants, and administering individual orientation and laboratory sessions to collect data. Participants were required to complete three tasks: attend a 45-minute orientation session, wear a non-invasive armband sensor for three consecutive days, and participate in 90-minute laboratory session.

At the close of Year 1, data collection was nearly complete with data analysis expected to start early in the next quarter. Although there are no major findings to report at this time, the project has been successful in reaching its' recruitment and data collection goals thus far.

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The approved Statement of Work for this contract is divided into 15 Tasks, which includes 5 Deliverables. This annual report describes the research tasks and results from Year 1 activities (August 6, 2007 to August 5, 2008). Tasks 1-10 were carried out during Year 1 of the project. At the close of the first year, data collection was nearly complete, and analyses on the data is set to occur over the next six months with Tasks 11-15 being addressed during this period.

## **Task 1: Human subjects' protocol review and approval (16 weeks)**

Human subjects' protocol was submitted to the University of Hawai'i for IRB approval on October 4, 2007. The protocol received expedited approval on October 24 (Appendix A).

On November 15, 2007, the human subjects' protocol was sent to Brigit Ciccarello, a regulatory Compliance Specialist for TATRC, for feedback and revisions. Ms. Ciccarello submitted the protocol on January 31, 2008, with a request for a quick turnaround. On March 25, Caryn Duchesneau, Chief of the Human Subjects Protection Review, informed the research team that the protocol was approved and it complied with applicable Federal, DOD, U.S. Army, and USAMRMC human subjects' protection requirements (Appendix B).

Protocol and IRB approval from both the University of Hawai'i and USAMRMC were submitted as a Deliverable on April 3, 2008.

A continuing review report will be submitted to the University of Hawai'i and USAMRMC prior to October 24, 2008.

## **Task 2: Development of a participant recruitment and retention plan (12 weeks)**

Recruitment materials from the 2005 pilot study were revised and adapted for use in the current project. Advertisements, flyers, and public service announcements were displayed around campus and in the local community. The most frequently used advertisement was a one-page flyer that included information on what was required of participants, who was eligible, and details for how to contact the research assistant (Appendix C). This ad was displayed on bulletin boards around campus and in various media outlets (i.e. student newspaper and radio). Language for all print advertising material was approved in the original Protocol.

A detailed Recruitment and Retention plan was written and submitted as a Deliverable on April 3, 2008. No revisions were necessary over the course of the study.

## **Task 3: Equipment order and acquisition (9 weeks)**

All of the equipment was purchased and obtained during the second and third quarters of this project. The main equipment purchases included a desk-top computer, a projector, a reclining armchair, a DVD player, shoji screens, noise canceling headphones, and physiological sensors from Thought Technology, Inc. It was determined that it would be best to show the film clip presentation using a projector and screen rather than a large television as initially planned. This was not only more practical, but resulted in substantial cost-savings. It was not necessary to purchase additional armband sensors as there were still remaining armbands from the pilot study.

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The Project Manager, Rebekah Rodericks, practiced using all of the equipment prior to the start of the orientation and laboratory sessions. Most of the equipment was straightforward to use, but the biofeedback equipment required a brief training session. An employee from Thought Technology provided a one-on-one training session with Ms. Rodericks regarding the use of the physiological sensors and software program.

## **Task 4: Development of mediated intervention materials (12 weeks)**

There were two activities incorporated into the project's laboratory sessions. The first was an elicited stress activity (i.e. a public speaking exercise), which was used to provide physiological data associated with a standardized, identifiable stress response. This stress event was elicited by having each participant prepare to deliver a speech under considerable time pressure.

Studies of smokers in both laboratory and naturalistic environments have confirmed a positive relationship between exposure to smoking cues and measurable changes in subjective and physiological responses (e.g., Baumann & Sayette, 2006; Bordnick, et al., 2005; Dols, Willems, van den Hout, & Bittoun, 2000; Harakeh, Engels, van Baaren, & Scholte, 2007). With this in mind, it was decided that the second laboratory activity would be a presentation of short film clips shown in an enhanced media environment (i.e. large screen, comfortable armchair, dark room). Based on the literature in the field (Rottenberg, Ray, & Gross, 2006; Shadel, Niaura, & Abrams, 2001; Gross & Levenson, 1995), approximately 75 films were viewed in order to find film clips that elicited amusement, fear, and demonstrated scenes of smoking. Due to the amount of validated films that were considered outdated, it took longer than anticipated to find a satisfactory list of films. Once the list of potential films was narrowed down, the research team viewed the films together and agreed upon the most appropriate selection.

Mr. Kevin Luke was hired as a video consultant to edit and put together the final film clip presentation. Mr. Luke and Ms. Rodericks met several times to edit the films before completing the final version of the presentation. A pilot screening of the film clip presentation took place with several colleagues who were able to provide useful feedback, which was incorporated into the final version of the presentation.

The end result was 12 targeted clips that were each preceded by a 30-second neutral film clip in order to minimize any potential carry over effects from the previous film. The clips ranged from 30 seconds to two minutes in length. Four clips were used to introduce craving (showed images of cigarettes or smoking), four clips were used to elicit positive stress (amusement), and four were used to elicit negative stress (fear). Defining a stress event in the laboratory enabled the researchers to compare deprived and non-deprived smokers on their psychological interpretations of arousal. Participants rated their stress valence and arousal using the Self-Assessment Manikin (SAM) rating scale.

A detailed account of the film clip presentation was described in the Deliverable, "Development of mediated intervention materials". This Deliverable was submitted on April 3, 2008, along with a hard copy of the film presentation (DVD).

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## **Task 5: Script preparation (12 weeks)**

Standardized scripts were prepared for all stages of contact between the Project Manager (PjM) and the study participants. These scripts served as a guide to ensure the PjM remained consistent when speaking with each participant. A phone script was also used to guide the conversation when individuals called to inquire about participating in the project. This allowed the PjM to screen potential participants and confirm eligibility status in a consistent manner. Scripts were also necessary during the orientation and laboratory sessions. One script was used for the laboratory sessions and two scripts were used for the orientation sessions; one for smokers, and the other for both non-smokers and former smokers. The participants were informed that a pre-written script of information would be followed in order to keep the content standard for all participants; however they were encouraged to interrupt at any point if they had any questions or concerns. The language in all of scripts was included in the original Protocol approved by HRPO.

## **Task 6: Recruitment of participants (18 weeks)**

Participant recruitment was conducted primarily on the University of Hawai'i, Mānoa campus between April and August, 2008. Prospective participants were required to meet the following inclusion criteria in order to be considered eligible for participation in the study:

- Adults 18 and older,
- Able to attend a 90-minute lab session,
- Willingness to wear an armband sensor for three days,
- Self-reported good health or excellent health, and
- Ability to read, understand and complete all self-report questionnaires.

The study aimed to recruit current smokers, former smokers, and non-smokers. The definition of a smoker for purposes of this study is an individual who self-reports smoking a minimum of 10 cigarettes a day. Former smokers were identified as those who quit smoking cigarettes at least 6 months prior to recruitment. Before the intervention phase, smokers in the study were divided into two groups; deprived and non-deprived smokers. A deprived smoker was an individual who was randomly selected to refrain from smoking for 6 hours prior to their laboratory session. Non-deprived smokers were asked to continue with their normal smoking routine.

Prospective participants were considered ineligible if they were undergoing Nicotine Replacement Therapy for smoking cessation, and/or reported any smoking-related health conditions such as asthma, low cardiorespiratory fitness, or heart disease.

A participant database was continuously updated in order to track participant information. A total of 68 participants volunteered for the study prior to August 5, 2008, with 66 completing both the orientation and laboratory sessions. The following is a categorical breakdown of participants by demographics.

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1. Total number of participants = 66
2. Mean age: 34.14 years
3. Gender: 56% female
4. Mean education: 16.14 years
5. Mean BMI: 24.45
6. Marital Status: 80% not married
7. Ethnicity: 51% White: 15% Japanese; 11% Chinese: 1.5% African-American/Black, 1.5% Pacific Islander, 6% Other
8. General Health (self-report): 75% good/very good; 19.5% excellent; 2.4% fair
9. Employment: 50% Students; 26% employed full-time
10. Income: 77% annual household income < \$40,000
11. Group
  1. Never Smoker (n=24)
  2. Former Smoker (n=15)
  3. Smoker (n=12)
  4. Smoker (deprived) (n=15)

## **Task 7: Baseline data collection and equipment training for participants (9 weeks)**

The first participant orientation took place on April 12, 2008 and the session continued steadily through August. During this period, baseline data was continuously collected from orientation questionnaires and from armband sensors. The 45-minute orientation session provided an introduction to the study, gave training on how to use an armband sensor, and required several questionnaires to be filled out once informed consent had been received. Four questionnaires were used for baseline data collection: Smoking History and Behavior (BCC-LM), Situational Self-Efficacy (temptations), Questionnaire on Smoking Urges, and a Demographics questionnaire. After the orientation, each participant wore the armband sensor for 3 consecutive days in a naturalistic setting which allowed them to continue with their normal every day routines.

## **Task 8: Laboratory study portion (12 weeks)**

In January, 2008, laboratory space was arranged through the University of Hawai'i's Department of Public Health and Epidemiology. Dr. Stefan Keller (a co-Investigator) acted as a department liaison to ensure that all arrangements for the space were completed. Dr. Keller was also available to provide consultation on stress, smoking and behavioral change, if necessary. Access to the laboratory room was limited to the research team and onsite supervisor to promote privacy for the participants and contribute to the safety and storage of equipment.

The room itself was 9.5 feet by 14.5 feet and was an ideal size for the equipment needs and activities of the research project. The arrangement of the room allowed the research team to set up several shoji screens enabling the PjM to sit behind the screen and monitor the physiological sensors, while the participant sat on the opposite side and viewed the film clip presentation.



# BODY

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Digital photographs were taken of the laboratory room in order to help capture and record the arrangement of the room and to make note of the equipment being used. An electronic photo journal was completed with the intention of providing a better understanding of the equipment and layout of the research room to those unable to visit the location (Appendix D).

The first laboratory session took place on May 8, 2008. The length of each session was approximately 75-80 minutes. During the lab session, the sensors (EKG, respiration, and blood volume pulse) were briefly calibrated before participants engaged in two main activities designed to elicit arousal: a public speaking activity and a film clip presentation. Two questionnaires (Smoking Urges and Sense of Presence Inventory) were completed at the end of the session.

## **Task 9: Baseline data preparation**

Dr. Patricia Jordan created 3 databases on SPSS for use in managing and analyzing questionnaire data: one for baseline orientation; one for follow-up; and one for the film clip ratings during the laboratory session.

Orientation questionnaires were numbered with the participant's ID and smoking status, and then stored in a locked cabinet while awaiting analysis. Questionnaire data was entered manually by Dr. Jordan and Ms. Rodericks.

When participants finished their 3-day naturalistic baseline data collection, data from the armband was downloaded, exported, and stored directly onto the computer. The armbands were then cleared of the data for the next participant.

## **Task 10: Laboratory data preparation**

Similar to the orientation questionnaires, the lab questionnaires were numbered with the participant's ID and smoking status, and then stored in a locked cabinet.

After each laboratory session, data from the physiological sensors and the armband were saved and exported. Due to the large size of the data from the physiological sensors, it was decided that the data from each participant would also be saved onto a DVD as a backup.

**Tasks 11-15:** By the end of this reporting period, data collection and data entry were almost complete, with data analysis soon to follow. Tasks 11-15 refer to data analysis, algorithm development, and preparation of the final report, which will be addressed over the upcoming months.

**Task 11: Delivery of data to TATRC – N/A**

**Task 12: Longitudinal data analysis – N/A**

**Task 13: Algorithm development and testing – N/A**

**Task 14: Preparation of final report – N/A**

**Task 15: Delivery of final report – N/A**

# KEY RESEARCH ACCOMPLISHMENTS

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## Equipment and Research Space

- Before data collection could begin, a variety of equipment was purchased and obtained during the period of December, 2007 to May, 2008. Even though recruitment did not begin until April 2008, it was important to acquire the equipment at an early stage so the research team could gain familiarity with the physiological sensors and software.
- In January, 2008, the Department of Public Health and Epidemiology at the University of Hawai'i agreed to allow the research team to use one of their small conference rooms to conduct meetings with the study participants.

## Recruitment Efforts

Sixty-eight participants have been recruited, with sixty-six having completed the study during Year 1 of the project. These participants were divided into 4 groups; never smokers, former smokers, and current smokers (who were randomized into deprived smokers and non-deprived smokers).

1. Never Smoker (n=24)
2. Former Smoker (n=15)
3. Smoker (n=12)
4. Smoker (deprived) (n=15)

# REPORTABLE OUTCOMES

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## Administrative Comments

- Rebekah Rodericks and Elizabeth Stone were hired as co-Project Managers at 50% FTE each, effective October 16, 2007. One month later, Elizabeth Stone resigned from her position and Ms. Rodericks increased her effort on the project to 100% as Project Manager.
- Towards the end of Year 1, the research team began searching for qualified biostatisticians to conduct data analyses. The selected candidate is expected to begin October 1, 2008.
- The project's timetable has been slightly adjusted as deadlines have shifted over the course of the study (Appendix E); for example, due to a delay in submitting the protocol (caused by problems with TATRC's email system in December, 2007), there was a one month delay in receiving human subjects' approval, which postponed recruitment. It was expected that data collection would be finished by the end of August, 2008, however, the Department of Public Health at the University of Hawai'i has offered the use of the research room for one additional month if necessary (until the end of September, 2008).

## Deliverables and Quarterly Reports

- Three Deliverables were submitted on April 3, 2008.
  1. Human Subjects Protocol Review and Approval
    - Local IRB (University of Hawai'i) and USAMRMC
  2. Recruitment and Retention Plan
    - Outline and agenda for recruiting and retaining study participants
  3. Development of Mediated Intervention Materials
    - Mediated stress activity and elicited stress activity
- Three Quarterly Reports were submitted to Dr. Stan Saiki and Glenn Kim during Year 1.
  1. Quarterly Report 1 was submitted on November 15, 2007.
    - This report summarizes the progress of the study from Aug. 1 to Oct. 31, 2007.
  2. Quarterly Report 2 was submitted on February 15, 2008.
    - This report summarizes the progress of the study from Nov. 1 to Jan. 31, 2008.
  3. Quarterly Report 3 was submitted on May 15, 2008.
    - This report summarizes the progress of the study from Feb. 1 to April 30, 2008.

## Conference Presentations

- March 26-29, 2008: Dr. Jordan presented at the 29<sup>th</sup> Annual Meeting for Society of Behavioral Medicine in San Diego to present findings from the BIOSEN pilot project.
  1. Paper presentation on March 28 at 1:30pm. Paper was part of Paper session #20: From Biology to Population: Current Topics in Tobacco Research. Paper was entitled:

# REPORTABLE OUTCOMES

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Psychophysiological Prediction of Smoking a Cigarette, and was awarded a Citation for significance and originality (Appendix F).

- June 23-26, 2008: Ms. Rodericks presented at the 13<sup>th</sup> Annual CyberTherapy Conference in San Diego. She presented an overview of BIOSEN II's methodology and showed a short film excerpt to demonstrate the principal of cue exposure.
  1. Ms. Rodericks presented in a panel presentation on June 23, 2008 from 4:00-5:30pm. The presentation was entitled: Psychophysiological Aspects of Tobacco Use and Craving (Appendix G).

## Preliminary Analysis of Baseline Demographics

As soon as questionnaires were completed, baseline data was manually entered into SPSS software. Listed below are the results of several preliminary analyses. It is too early to make any interpretations of the data at this point in the study.

Of the 66 total participants, 27 were current smokers. Smokers in this study rated a moderate level of nicotine tolerance with a mean nicotine tolerance score of 5.3 at baseline. According to the Fagerström Tolerance Scale (Fagerström & Schneider, 1989), individuals who score between 4-6 indicate a medium level of addiction. Participants also reported little readiness to change their smoking behavior, and self-selected into the following groups.

Precontemplation stage of change (n=15)  
Contemplation stage of change (n=9)  
Preparation stage of change (n=3)

Preliminary analyses show that there were no significant differences between the three groups (Never Smoker, Former Smoker, and Smoker) on measures of Body Mass Index (BMI); but significant differences were found between the three groups in Education and Age. For example, Former Smokers reported having significantly more years of education than Smokers [ $M_{\text{former}}=17.40$  (1.68),  $M_{\text{smoker}}=15.59$  (2.23);  $p<.05$ ]. Former Smokers were also significantly older than both Never Smokers and Smokers [ ( $M_{\text{former}}=42.4$  (13.19),  $M_{\text{smoker}}=32.67$  (12.80),  $M_{\text{never}}=30.63$  (11.46);  $p<.05$ )]. When comparing the two groups of smokers (non-deprived and deprived), there were no significant differences on Education, Age, BMI, Fagerström score, Temptations Scale, or Smoking Urges.

As data collection continues, further analyses of the data will be conducted.

# CONCLUSION

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The progress and accomplishments during the first year of the project “Transformative Learning: Patterns of Psychophysiological Response in Technology Enabled Learning and Intervention Systems” have focused primarily on data collection. By the end of the reporting period in August 2008, data was still being collected and early stages of data analysis were in progress. For this first year of performance, data have been collected for 66 participants.

The data from this study will refine statistical algorithms that can be incorporated into a wireless sensor device to provide individualized feedback to foster behavior change at an optimal moment (i.e., when physiological craving is elevated). What makes this a novel approach is that many smoking interventions to date have been developed based on normative data or a standard approach meant to work for everyone. The data collected from this research study intend to contribute to the development of smoking cessation interventions that will be more applicable on an individual, tailored basis in the future.

While there are no preliminary findings to report at this time, it is anticipated that the data from this study will identify individual patterns of tobacco use and craving, which will be promising in developing interventions at the earliest point of arousal. This may allow individuals to seek help before the full spiral of addictive behavior spins out of control. This is important not only for those trying to quit smoking, but this knowledge may also be applicable to other addictions and substance abuse patterns. As modifiable behaviors such as smoking, alcohol, and obesity continue to contribute to nearly half of American deaths, it is hoped that developing innovative treatments and interventions that address behavior change will be beneficial to the population as a whole.

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# **APPENDICES**

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**APPENDIX A: University of Hawai'i IRB Approval**

**APPENDIX B: USAMRMC Protocol Approval**

**APPENDIX C: Advertisement for Recruitment**

**APPENDIX D: Electronic Photo Journal**

**APPENDIX E: Project Timeline**

**APPENDIX F: Presentation for Society of Behavioral Medicine Conference**

**APPENDIX G: Presentation for CyberTherapy Conference**

**APPENDIX A: University of Hawai'i**  
**IRB Approval**



# UNIVERSITY OF HAWAII

Committee on Human Studies

## MEMORANDUM

October 24, 2007

TO: Lawrence Burgess, M.D.  
Leigh W. Jerome, Ph.D.  
Principal Investigators  
Telehealth Research Institute

FROM: William H. Dendle  
Executive Secretary

SUBJECT: CHS #15572- "Patterns of Psychophysiologic Response in Technology-Enabled Learning and Intervention Systems"

Your project identified above was reviewed by the Chair of the Committee on Human Studies through Expedited Review procedures. The project qualifies for expedited review by CFR 46.110 and 21 CFR 56.110, Category (4) of the DHHS list of expedited review categories.

This project was approved on October 24, 2007 for one year. If in the active development of your project you intend to change the involvement of humans from plans indicated in the materials presented for review, prior approval must be received from the CHS before proceeding. If unanticipated problems arise involving the risks to subjects or others, report must be made promptly to the CHS, either to its Chairperson or to this office. This is required in order that (1) updating of protective measures for humans involved may be accomplished, and (2) prompt report to DHHS and FDA may be made by the University if required.

In accordance with the University policy, you are expected to maintain, as an essential part of your project records, all records pertaining to the involvement of humans in this project, including any summaries of information conveyed, data, complaints, correspondence, and any executed forms. These records must be retained for at least three years from the expiration/termination date of this study.

The CHS approval period for this project will expire on October 24, 2008. If your project continues beyond this date, you must submit a continuation application to the CHS at least four weeks prior to the expiration of this study.

We wish you success in this endeavor and are ready to assist you and your project personnel at any time.

Enclosed is your certification for this project.

Enclosure

**Protection of Human Subjects**  
**Assurance Identification/IRB Certification/Declaration of Exemption**  
**(Common Rule)**

*Policy:* Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (58FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type <input checked="" type="checkbox"/> ORIGINAL <input type="checkbox"/> CONTINUATION <input type="checkbox"/> EXEMPTION	2. Type of Mechanism <input checked="" type="checkbox"/> GRANT <input type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOWSHIP <input type="checkbox"/> COOPERATIVE AGREEMENT <input type="checkbox"/> OTHER: _____	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.  Hawaii Federal Healthcare Network / TATRC-USAMRMC
4. Title of Application or Activity "Patterns of Psychophysiologic Response in Technology-Enabled Learning and Intervention Systems"		5. Name of Principal Investigator, Program Director, Fellow, or Other  Lawrence Burgess, M.D. / Leigh W. Jerome, Ph.D.

6. Assurance Status of this Project (Respond to one of the following)


- ☒ This Assurance, on file with Department of Health and Human Services, covers this activity:  
 Assurance Identification No. F-3526, the expiration date September 23, 2008 IRB Registration No. IORG0000169
- ☐ This Assurance, on file with (agency/dept) \_\_\_\_\_, covers this activity.  
 Assurance No. \_\_\_\_\_, the expiration date \_\_\_\_\_ IRB Registration/Identification No. \_\_\_\_\_ (if applicable)
- ☐ No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.
- ☐ Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph \_\_\_\_\_.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

- ☒ This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.  
 by: ☐ Full IRB Review on (date of IRB meeting) \_\_\_\_\_ or ☒ Expedited Review on October 24, 2007  
☐ If less than one year approval, provide expiration date \_\_\_\_\_
- ☐ This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

CHS #15572

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.		10. Name and Address of Institution  University of Hawaii at Manoa 2444 Dole Street, Bachman Hall Honolulu, HI 96822
11. Phone No. (with area code)	(808) 956-5007	
12. Fax No. (with area code)	(808) 956-8883	
13. Email:	dendie@hawaii.edu	
14. Name of Official  William H. Dendle		15. Title  Compliance Officer
16. Signature 		17. Date October 24, 2007

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## **APPENDIX B: USAMRMC Protocol Approval**

**A-14433, HRPO Approval Memorandum (Proposal Log  
Number 06263008, Award Number W81XWH-07-2-0086)  
(UNCLASSIFIED)**

Classification: UNCLASSIFIED

Caveats: NONE

SUBJECT: Initial Approval for the Protocol, "Patterns of Psychophysiologic Response in Technology Enabled Learning and Intervention Systems," Submitted by Leigh W. Jerome, PhD, University Clinical, Education, and Research Associates (UCERA), Honolulu, Hawaii, in Support of the Proposal, "Transformative Learning: Patterns of Psychophysiologic Response in Technology-Enabled Learning and Intervention Systems," Proposal Log Number 06263008, Award Number W81XWH-07-2-0086, HRPO Log Number A-14433

1. The subject protocol (version approved 24 October 2007) was approved by the University of Hawaii Committee on Human Studies (CHS) on 24 October 2007. This protocol was reviewed by the U.S. Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) and found to comply with applicable Federal, DOD, U.S. Army, and USAMRMC human subjects protection requirements.

2. This no greater than minimal risk study is approved for the enrollment of up to 102 subjects (minimum of 23 subjects per group).

3. Please note the following reporting obligations:

a. Major modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the USAMRMC ORP HRPO for approval prior to implementation.

All other amendments must be submitted with the continuing review report to the HRPO for acceptance.

b. All unanticipated problems involving risks to subjects or others, serious adverse events related to study participation, and deaths related to study participation must be reported promptly to the HRPO.

c. Any deviation to the subject protocol that affects the safety or rights of the subject and/or integrity of the study data must be reported promptly to the HRPO.

d. All modifications, deviations, unanticipated problems, adverse events, and deaths must also be reported at the time of continuing review of the protocol.

e. A copy of the continuing review report approved by the University of Hawaii CHS must be submitted to the HRPO as soon as possible after receipt of approval. It appears the next continuing review by the University of Hawaii CHS is due no later than 24 October 2008.

f. In addition, the current version of the protocol and consent form (if applicable) must be submitted along with the continuing review report and the University of Hawaii CHS approval notice for continuation of the protocol.

g. The final study report submitted to the University of Hawaii CHS, including a copy of any acknowledgement documentation and any supporting documents, must be submitted to the HRPO as soon as all documents become available.

4. Do not construe this correspondence as approval for any contract funding. Only the Contracting Officer or Grants Officer can authorize expenditure of funds. It is recommended that you contact the appropriate contract specialist or contracting officer regarding the expenditure of funds for your project.

5. The HRPO point of contact for this study is Pamela Barretto-Jones, RN, MSN, Human Subjects Protection Scientist, at 301-619-1018/pamela.barrettojones@us.army.mil.

CARYN L. DUCHESNEAU, CIP  
Chief, Human Subjects Protection Review  
Human Research Protection Office  
Office of Research Protections  
U.S. Army Medical Research and Materiel Command

Note: The official copy of this approval memo is housed with the protocol file at the Office of Research Protections, Human Research Protections Office, 504 Scott Street, Fort Detrick, MD 21702. Signed copies will be provided upon request.

Classification: UNCLASSIFIED  
Caveats: NONE

## **APPENDIX C: Advertisement for Recruitment**



# Watch Movie Clips for Research



We are conducting a research study to compare patterns of emotional response between smokers and non-smokers. Current smokers, former smokers, and non-smokers are needed for this study. Participants in the study will wear an armband sensor for three days. Participants will also rate a series of movie clips.

We are seeking volunteers who meet the following criteria:

- Adults 18 and older
- Current smoker, former smoker, or nonsmoker
- Very good or excellent health status;
- Able to attend a 90-minute lab session

Individuals should not volunteer to participate if they:

- a) Are undergoing any treatment for smoking cessation; or
- b) Have any smoking-related health conditions  
(e.g., asthma, low cardio respiratory fitness, etc.)

The study will take place on the UH Mānoa campus. A stipend is available for time and travel. If you are interested in participating, please contact:

Becky Rodericks at 383-1861 or  
via email: [becky.rodericks@pacifichui.org](mailto:becky.rodericks@pacifichui.org)

Please note that this is not a treatment study.

University Clinical Education and Research Associates (UCERA)

Research Study  
[ Call Becky at 383-1861 ]

Research Study  
[ Call Becky at 383-1861 ]

Research Study  
[ Call Becky at 383-1861 ]

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## **APPENDIX D: Electronic Photo Journal**



## **Electronic Photo Journal**

### **Section 1: Equipment and Lab Setting**

Figure 1 - Research Room  
Figure 2 - SenseWear Pro2 Armband  
Figure 3 - Film Presentation Equipment  
Figure 4 - Thought Technology (Pro Comp Infiniti)

### **Section 2: Laboratory Activities**

Figure 5 - Public Speaking Activity  
Figure 6 - Film Presentation: Neutral Scenes  
Figure 7 - Film Presentation: Amusing Scenes  
Figure 8 - Film Presentation: Scary Scenes  
Figure 9 - Film Presentation: Smoking Scenes

### **Section 3: Research Tools**

Figure 10 - Sensor Display Book  
Figure 11 – Flyers  
Figure 12 - Public Service Announcement  
Figure 13 - Binder and Book Light  
Figure 14 - Select an Envelope at Random

### **Section 4: Data Collection and Storage**

Figure 15 - Thought Technology Data  
Figure 16 - Armband Data  
Figure 17 - Summary from Armband  
Figure 18 - Data Storage

**SECTION 1: Equipment and Lab Setting:** This section will provide a visual display of the laboratory setting to promote a better understanding of how the study is conducted. This section will also describe some of the main equipment that is required.

---

**Figure 1: Research Room**



**Figure 1:** This is an example of the research laboratory. Each participant sits in a reclining armchair for the duration of the session, wearing the SenseWear armband and 3 additional physiological sensors. On the side table sits a projector and DVD player. The participant wears headphones while watching the film clips and rates their responses in the binder on their lap. Behind the chair you will see several shoji screens which assist in dividing the lab space. The computer equipment is kept behind here and this is where the researcher sits while the participant views the film clip presentation.

**Figure 2: SenseWear Pro<sub>2</sub> Armband**



**Figure 2:** This is a SenseWear Pro<sub>2</sub> armband from Body Media. Participants wear this device on their upper right arm during the 3-day naturalistic phase of data collection, and during the lab session.

**Figure 3: Film Presentation Equipment**



**Figure 3:** A DVD player is connected to a projector, and a large screen is used to view the film clips.

**Figure 4: Thought Technology (Pro Comp Infiniti)**



**Figure 4:** This image shows biofeedback equipment from Thought Technology (Pro Comp Infiniti). It collects a range of physiological data from the participants during the lab session.

**SECTION 2: Laboratory Activities:** Now that the arrangement of the laboratory room has been described, this next section will give a pictorial display of the two main activities that occur in the laboratory session. The first is the elicited stress activity (i.e. public speaking activity), and the second is the mediated stress activity (i.e. film clip presentation).

---

**Figure 5: Public Speaking Activity**



**Figure 5:** Participants are told that they have 60 seconds to prepare a 3 minute speech on a specific topic. They are then informed that half of the participants will be selected to deliver their speech in front of the webcam while using headphones and a microphone. They are told that the speech will later be evaluated by the research team. No participants are required to give their speech.

**Figure 6: Film Presentation: Neutral Scenes**



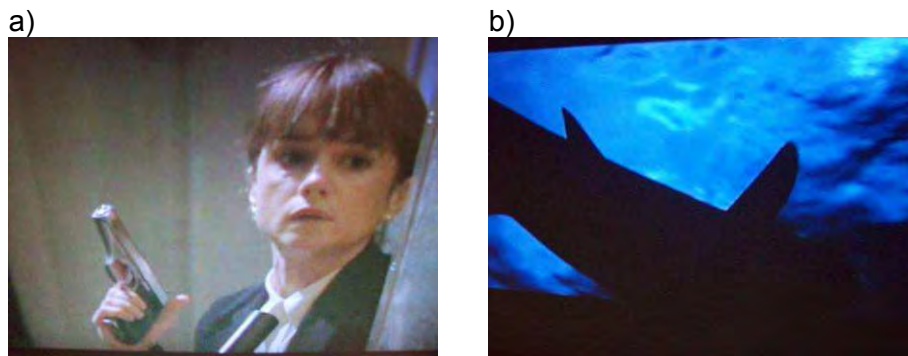
**Figure 6:** The 3 images above are examples of neutral clips that were used in the film clip presentation.

**Figure 7: Film Presentation: Amusing Scenes**



**Figure 7:** Examples of films that elicit amusement: a) Bill Cosby, b) Seinfeld, and c) There's Something About Mary.

**Figure 8: Film Presentation: Fear Scenes**



**Figure 8:** Examples of films that elicit fear: a) Copycat, and b) Open Water.



**Figure 9: Film Presentation: Smoking Scenes**

a)



b)



c)



d)

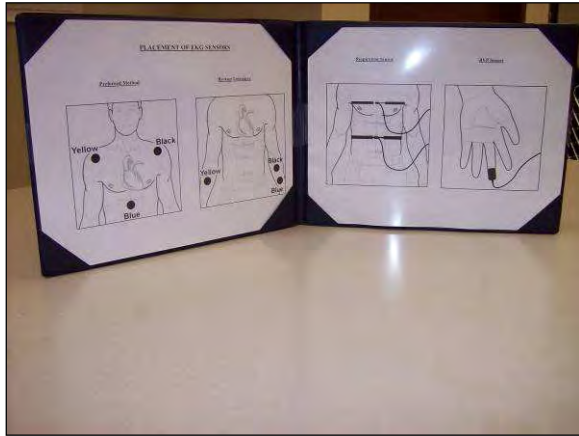


**Figure 9:** Examples of films that demonstrate smoking: a) Royal Tennenbaums, b) Coffee and Cigarettes, c) Bridget Jones Diary, and d) My Best Friend's Wedding.

**SECTION 3: Research Tools:** In order to run an effective lab session, small research tools and props aid the success of the study.

---

**Figure 10: Sensor Display Book**



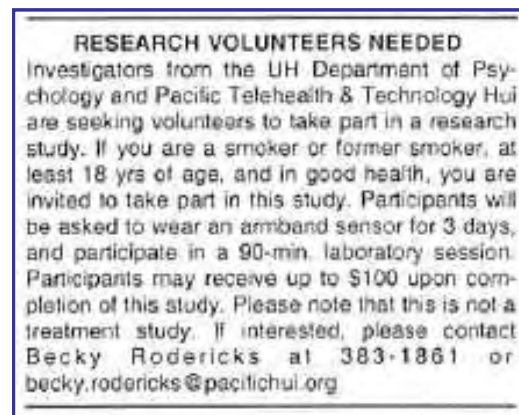
**Figure 10:** A display book is used to demonstrate to the participants what physiological sensors will be used and where they will be placed. This has been very helpful in the both the orientation and laboratory sessions in order for the participants to comprehend what is expected of them.

**Figure 11: Flyers**



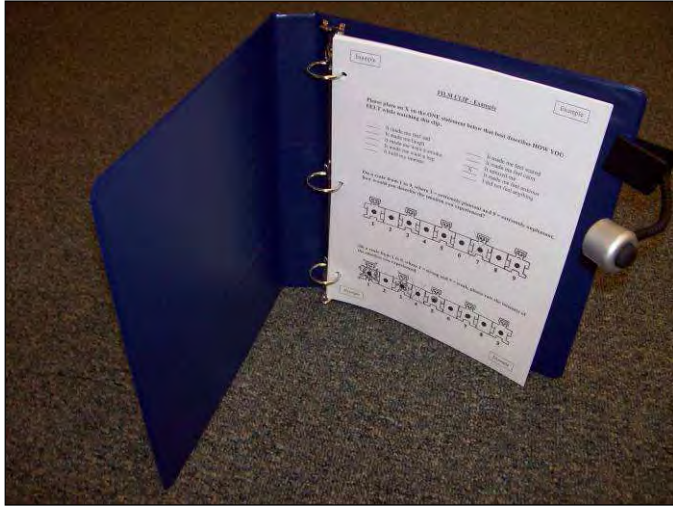
**Figure 11:** Flyers have been posted around the UH campus and in various locations in the community to inform the public about the study.

**Figure 12: Public Service Announcement**



**Figure 12:** An advertisement was placed in the UH student newspaper, *Ka Leo*, for several consecutive weeks to increase participation.

**Figure 13: Binder and Book Light**



**Figure 13:** This 3-ring binder provides all of the information the participants need during the film clip presentation. There is one sheet of paper for each of the 25 short clips. The participants must answer 3 questions for every film clip. On the right of the binder, you will see an object that is a book light. The overhead light in the room is turned off during the film clip presentation to provide an enhanced media environment. Therefore the book light allows the participants to see the questions they must answer after each film clip, without having to interrupt them to turn on the overhead light.

**Figure 14: Select an Envelope at Random**



**Figure 14:** A simple method was adopted to randomly select 50% of smokers to refrain from smoking. Participants are instructed to pick any envelope at random to find out if they must refrain from smoking for 6 hours before the lab session.



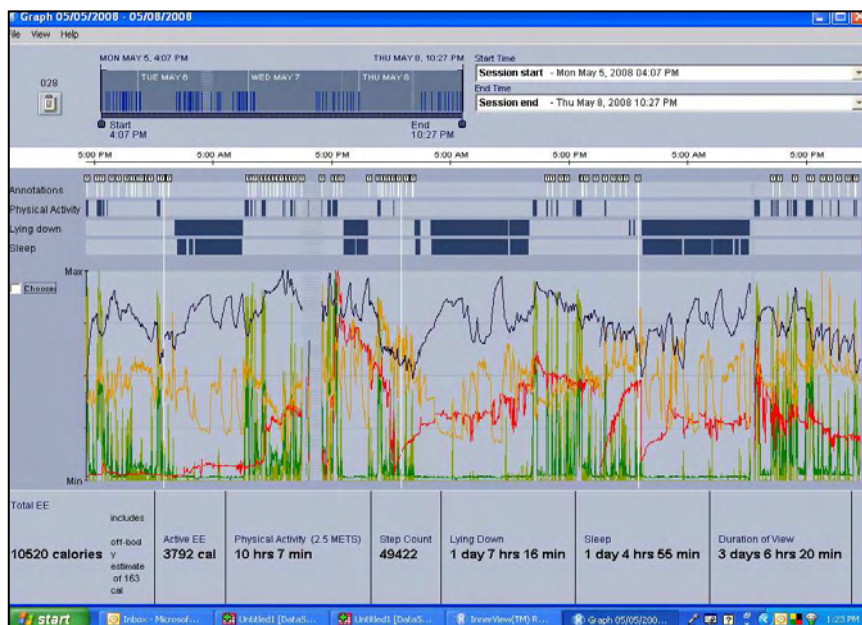
**SECTION 4: Data Collection and Storage:** This section shows examples of several graphs and charts that are produced during or after the data collection phase.

**Figure 15: Thought Technology Data**



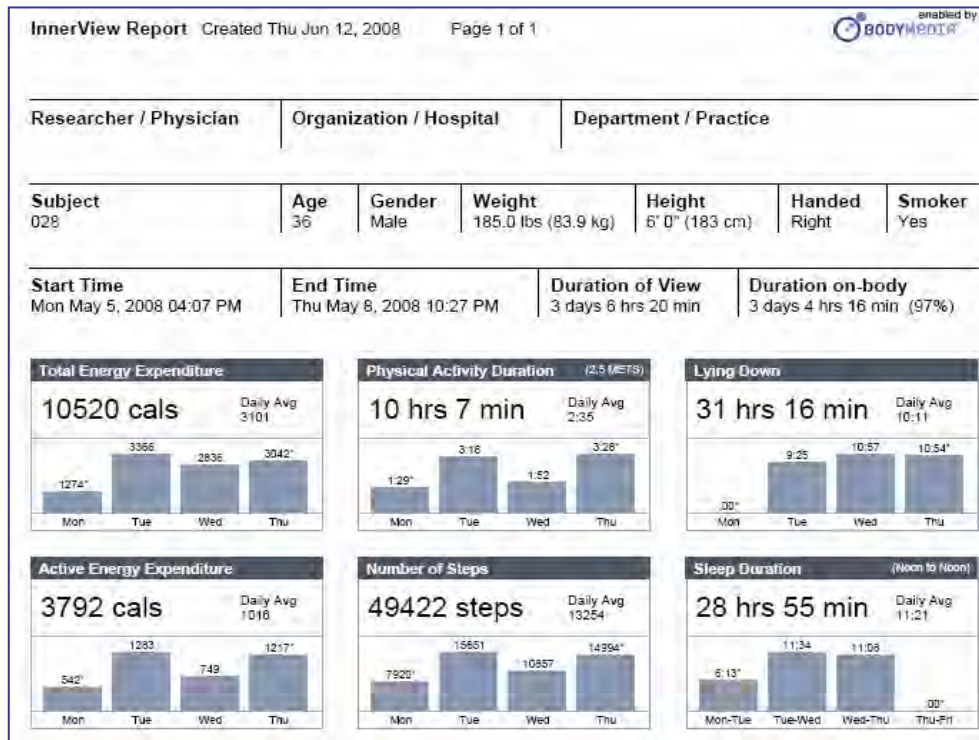
**Figure 15:** While wearing the physiological sensors, the computer continuously monitors the data from each participant. Shown on the left is an example of the information that is actively collected while the sensors are in use.

**Figure 16: Armband Data**



**Figure 16:** This image is produced when the armband data is downloaded. These graphs show statistics such as skin temperature, energy expenditure, and can even timestamp and record the moment when participants smoked each cigarette during the course of the day.

**Figure 17: Summary Data**



**Figure 17:** This chart summarizes the individual results for each participant when they wore the armband for 3 days. Participants will be provided with a PDF version at the conclusion of the study.

**Figure 18: Data Storage**




**Figure 18:** As soon as each participant finishes the lab session, the data from the physiological sensors is stored not only on the computer, but also exported and saved onto a DVD. The file size is very large so each participant has their own individual DVD.

## **APPENDIX E: Project Timeline**

ID	Task Name	Start	Finish	Duration	Q4 07			Q1 08			Q2 08			Q3 08			Q4 08			Q1 09		
					Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
1	Human Subjects Protocol Approval	8/22/2007	3/25/2008	155d																		
2	Develop recruitment and retention plan and recruitment materials	12/3/2007	4/2/2008	88d																		
3	Equipment order and acquisition	12/3/2007	5/1/2008	109d																		
4	Mediated intervention materials	12/3/2007	4/2/2008	88d																		
5	Standardized script preparation	10/1/2007	4/10/2008	139d																		
6	Recruitment of participants	3/3/2008	8/29/2008	130d																		
7	Baseline data collection and training	4/15/2008	8/15/2008	89d																		
8	Laboratory data collection	4/18/2008	8/29/2008	96d																		
9	Baseline data preparation	5/22/2008	9/15/2008	83d																		
10	Laboratory data preparation	5/22/2008	1/15/2009	171d																		
11	Data delivery	9/3/2008	9/3/2008	1d																		
12	Data analysis	9/15/2008	3/13/2009	130d																		
13	Continuing Review (IRB)	9/30/2008	10/24/2008	19d																		
14	Algorithm development & testing	11/3/2008	3/13/2009	95d																		
15	Preparation of final report	3/13/2009	4/29/2009	34d																		
16	Delivery of Final Report	4/30/2009	4/30/2009	1d																		

**APPENDIX F: Presentation for  
Society of Behavioral Medicine Conference**





# Psychophysiological Prediction of Smoking a Cigarette

Patricia J. Jordan, Ph.D.  
Pacific Telehealth & Technology Hub; Honolulu, HI

Leigh W. Jerome, Ph.D.  
The Institute for Triple Helix Innovation; Honolulu, HI

Stephen Korow, M.B.A.  
Decision Research Corporation; Honolulu, HI

Funding provided by the USAMRMC (TATRC) (Contract No. V549P-6841)

## Introduction

- *Smoking is the leading cause of preventable disease, disability, and death in the U.S.<sup>1</sup>*
- *21% of U.S. adults are smokers<sup>1</sup>*
  - *70 % of all smokers would like to quit<sup>2</sup>*
  - *4% quit smoking permanently<sup>2</sup>*
- *Approximately \$157 billion in annual health-related economic losses*
  - *More than one-half of which is medical expenditures<sup>2</sup>*

Society of Behavioral Medicine • March 26-29, 2008

2

## Introduction

- *Two decades of research have led to the pharmacological and behavioral tools that can effectively treat nicotine addiction.*
- *Treatment can increase long-term success rates from 7% to as high as 30%.<sup>3</sup>*

Society of Behavioral Medicine • March 26-29, 2008

3

## Intervention

- *Interventions are underutilized, and do not serve the needs of a majority of smokers.*
- *Individually tailored interventions prove more successful than non-tailored or no interventions.<sup>4</sup>*

Society of Behavioral Medicine • March 26-29, 2008

4

## Intervention Delivery

- *Emerging technologies offer new opportunities for delivering tailored behavioral interventions.<sup>5</sup>*
- *Allow us to tailor feedback to an individual's biometrics and daily routines to match opportune moments for effective intervention.*

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5

## Tobacco Use & Craving

- *Research using biosensors suggests that the arousal associated with specific behavioral events can be accurately detected and predicted.<sup>6-8</sup>*

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6

## Craving and Arousal

- *Specific physiologic patterns associated with craving have been previously described but not identified.*
- *The relationship between smoking and stress may provide evidence for the arousal patterns related to cravings.<sup>9</sup>*

## Research Aims

- *Detect the physiological antecedents that prompt smokers to use tobacco through the analysis of biometric and behavioral data.*
- *Develop a conceptual model for establishing new approaches to smoking intervention.*

## Research Design

- *Collection of biometric and cognitive/behavioral data*
  - *Baseline questionnaires*
  - *7 days of continuous wear of armband biosensor*
  - *Participants pushed an "event button" on the armband each time they lit a cigarette.*
- *Collection of 3-month follow-up data*
  - *4 days' continuous sensor wear*
- *Data analysis and algorithm development*
  - *Identify and predict the arousal patterns associated with craving and/or tobacco use behavior*

## Participants

- *Nine participants completed Phase 1*
  - *67% male*
  - *32.9 years of age (SD=10.3)*
  - *15.3 years of education (SD=2.8)*
  - *Never married (55.6%); Divorced (33.3%)*
  - *55.6% reported in very good health*
  - *44.4% Student, 33.3% full-time*
  - *62.5% reported < \$40,000/annum*
  - *Caucasian (77.8%); 22.2% Hispanic (n=2)*

## Measurement

- *Smoking History and Behavior*
- *Fagerström Tolerance Scale*
- *Stage of Change*
- *7-Day Point Prevalence*
- *Confidence to quit*
- *Decisional Balance (pros and cons)*

## Measurement

- *BodyMedia SenseWear® Pro<sub>2</sub>*
  - *Heat flux*
  - *Skin temperature*
  - *Energy expenditure*
  - *GSR*
  - *Movement*



## Data Analysis

- *Discriminant Function Analysis*
- *Gaussian Transformations*
- *Multivariate Hierarchical Regression*
- *Algorithm Development*
- *Confirmatory analysis*

## Results

- *Average age started smoking=16.4 years (SD=3.6)*
- *Smoked an average of 15.3 years (SD=11.9)*
- *Smoke an average of 25.9 cigs. per day (SD=26.8)*
- *Quit smoking an average of 2.9 times (SD=6.6)*
- *Little or no readiness to change*
  - *Precontemplation (77.8%)*
  - *Contemplation (22.2%)*
- *Moderate to high level of nicotine dependence*
  - *mean nicotine dependence score of 4.6 (SD=2.5)*

## Results

- *Total Observations = 83,826*
- *Number of timestamps (events) = 932*
- *Gaussian smoothing combined adjacent data points as positive events.*
- *DFA indicated that predictors were able to predict a smoking event above chance.*

## Results

- *Physiologic 64% (Wilks'  $\lambda = .991$ )*
- *Psychosocial 69.4% (Wilks'  $\lambda = .976$ )*
- *Combined 68.9% (Wilks'  $\lambda = .964$ )*

## Results

- *An algorithm prototyping tool was created to generate regression models based on each individual's biometric data.*

Equation Fields	Weight	Time Lag (Seconds)
<input type="checkbox"/> Normalized accelerometer horizontal		
<input type="checkbox"/> Normalized accelerometer longitudinal		
<input checked="" type="checkbox"/> Heart Rate average rate	0.09	0
<input type="checkbox"/> Average horizontal accelerometer		
<input type="checkbox"/> Average longitudinal accelerometer		
<input type="checkbox"/> Average skin temperature		
<input checked="" type="checkbox"/> Transverse accelerometer MAO	0.17	0
<input type="checkbox"/> Longitudinal accelerometer MAO		
<input checked="" type="checkbox"/> Steps	1.340	0
<input checked="" type="checkbox"/> Average GSR	1.720	0
<input checked="" type="checkbox"/> Energy expenditure per minute	1.048	0

## Results

- *The algorithms were inconsistent at predicting smoking with short time lags.*
- *Accuracy in smoking prediction varied across participants from 21%-45%.*
- *Predictive ability increased by an average of 62% with a 15-minute window.*



## Conclusion

- *Prediction equations that utilize physiological and psychological data can lead to the development of tailored interventions.*

## BIOSEN-II

- *The study uses principles of cue reactivity to investigate the biometric signature associated with elicited stress and tobacco craving.*
- *It is anticipated that comparisons of physiological responses to stress and craving among different groups will enable researchers to differentiate arousal due to stress reactivity and craving.*

### *Contact information:*

*Patricia J. Jordan, Ph.D.*

*Pacific Telehealth & Technology Hui*

*[patricia.jordan@pacifichui.org](mailto:patricia.jordan@pacifichui.org)*

*(808) 433-7346*

**APPENDIX G: Presentation for  
CyberTherapy Conference**

# Psychophysiological Aspects of Tobacco Use and Craving

Leigh W. Jerome, Ph.D.  
The Institute for Triple Helix Innovation

Patricia J. Jordan, Ph.D. & Becky Rodericks, M.P.H.  
Pacific Telehealth & Technology Hui

Funding provided by the USAMRMC (TATRC) (W81XWH-07-2-0086)

## Overview

- Research has confirmed a positive relationship between exposure to smoking cues and changes in subjective and physiological responses in smokers.
- Cue exposure research is aimed at stimulating craving in participants under a various conditions.
- Comparisons of physiological responses to arousal in different groups may enable researchers to differentiate arousal due to stress reactivity and craving.
- This study uses principles of cue exposure and non-invasive sensors to investigate the biometric signature associated with elicited arousal and tobacco craving.

CyberTherapy 2008 / June 23-25, 2008

## Objectives

Can physiological responses to cue exposure be used to predict behavior?

Does psychophysiological arousal differ between smokers and non-smokers?

How do physiological arousal/craving patterns differ between deprived smokers and non-deprived smokers in response to smoking cues?

CyberTherapy 2008 / June 23-25, 2008

## Study Design

- **Non-Smokers (N=46)**
  - Never smokers (N=23)
  - Former smokers (N=23)
- **Current smokers (N=46)**
  - Non-deprived smokers (N=23)
  - Deprived smokers\* (N=23)
- **Two-phases of data collection**
  - 3-day naturalistic baseline data collection
  - Laboratory session aimed at inducing stress/craving

CyberTherapy 2008 / June 23-25, 2008

## Eligibility

- **Current smokers, non-smokers, and former smokers**
- **Smokers:** minimum of 10 cigarettes a day on average
- **Former smokers:** quit at least 6 months ago
- Self-described "good" health – no major medical conditions
- Not undergoing any form of nicotine replacement therapy
- Fluent in English
- 18 years +

CyberTherapy 2008 / June 23-25, 2008

## Recruitment

- Started in mid-April
- Flyers on bulletin boards
- Mass emails
- Classrooms
- Word of mouth
- Ad in campus newspaper
- PSA radio broadcast
- Bars, bus stops, and various areas where smokers congregate
- Participant stipend \$100



**RESEARCH VOLUNTEERS NEEDED**  
Investigators from the UH Department of Psychology and Pacific Telehealth & Technology Hui are seeking volunteers to take part in a research study. If you are a smoker or former smoker, at least 18 yrs of age, and in good health, you are invited to take part in this study. Participants will be asked to wear an ambulatory sensor for 3 days, and participate in a 90-min laboratory session. Participants may receive up to \$100 upon completion of this study. Please note that this is not a treatment study. If interested, please contact Becky Rodericks at 383-1861 or becky.rodericks@pacifichui.org

CyberTherapy 2008 / June 23-25, 2008



## Phase 1

### What is the Armband?

- BodyMedia SenseWear® Pro<sub>2</sub> Armband
- A multi-sensor wearable body monitor
- Collects physiological and lifestyle data
- Can timestamp specific events

### Requirements

- Worn for 3 days
- Smokers: press "timestamp button" every time they have a cigarette



CyberTherapy 2008 / June 23-25, 2008

## Phase 1

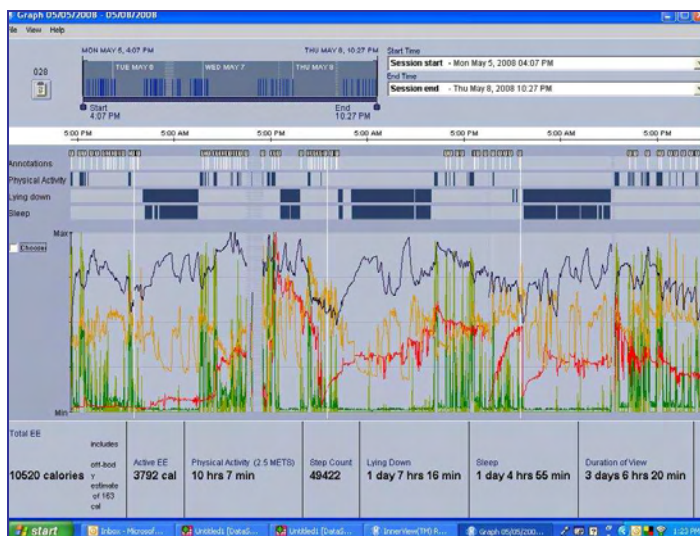
### What information is collected from the armband?

- movement
- heat flux
- skin temperature
- galvanic skin response
- sleep/wake cycles
- energy expenditure (e.g. calories burned)
- levels of physical activity (e.g. # of steps taken in a day)

### Participant Summary



CyberTherapy 2008 / June 23-25, 2008



## Phase 2

### Lab Sensors

- BodyMedia SenseWear® Pro<sub>2</sub>
- Thought Technology ProComp Infiniti
- Biofeedback sensors
  - EKG
  - Respiration
  - Blood Volume Pulse

### Two Main Lab Activities

- Elicited stress activity
- Mediated stress activity



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## Elicited Stress Activity

In the last 10 years, Hawaii has gone from being ranked the number 1 healthiest state in the nation to the 9th healthiest state (Morgan Quitno, 2007). You will have 60 seconds to prepare a 3-minute speech explaining why you think this decline has taken place.



"50% of the participants will be randomly selected to deliver their speech in front of a video camera (webcam). Your speech will be evaluated by the research team at a later date."

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## Mediated Stress Exposure

### 25 short film clips (≤ 2 minutes each/44 minutes total)

- (4) films elicit positive stress (i.e. amusement)
- (4) films elicit negative stress (i.e. fear)
- (4) film scenes that introduce cravings (i.e. scenes with smoking)
- (13) "neutral" clips

### After each clip, participants describe:

- emotional experience;
- level of arousal; and
- valence (positive or negative)

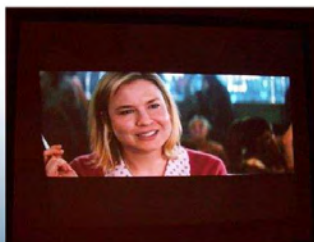
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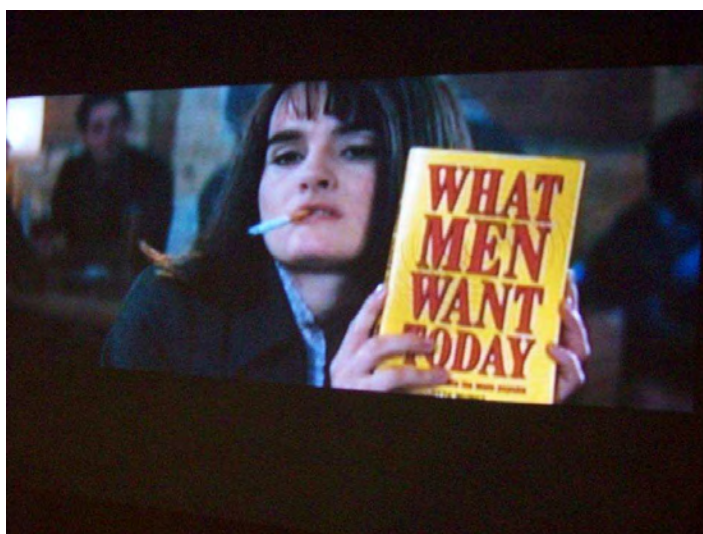
## FILM CLIPS

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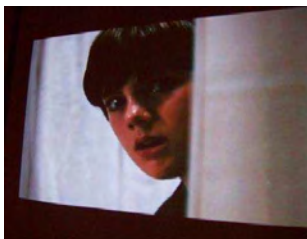
## Film clips: smoking scenes



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Films eliciting fear



## Films eliciting amusement

## Neutral film clip images

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## Conclusion

Standardized cue exposure provides a powerful paradigm to examine the multidimensional aspects of arousal and craving and to test the full scope, and mediating and moderating mechanisms of the relationship between substance use cues and craving.

If individual patterns of tobacco use and craving can be identified, opportunities exist for early intervention.

When combined with wearable sensors, cue exposure can assist in producing individualized, tailored feedback and help foster behavior change.

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## Mahalo...

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## Play examples of film clips

## Reference Slides

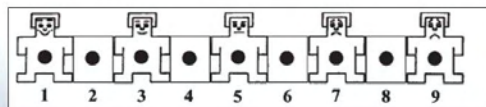
### Three Questions After Each Film Clip

1. Please place an X on the ONE choice below that best describes how you felt while watching this clip.

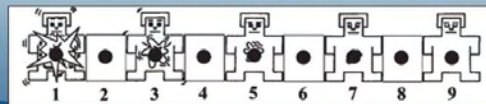
- ☐ It made me feel sad
- ☐ It made me laugh
- ☐ It made me want a smoke
- ☐ It made me want a nap
- ☐ It held my interest
- ☐ It made me feel scared
- ☐ It made me feel calm
- ☐ It made me feel happy
- ☐ It made me feel anxious
- ☐ I did not feel much of anything



2. On a scale of 1 to 9, where 1 = extremely pleasant and 9 = extremely unpleasant, how would you describe the emotion that you experienced?



3. On a scale of 1 to 9, where 1 = the strongest and 9 = the weakest, please rate the intensity of the emotion you experienced.



### Laboratory Setting